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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,131	10/02/2003	Hassan Jomaa	40770-000152/US/DVA	6018

23416 7590 08/11/2009

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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
08/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/676,131	JOMAA, HASSAN	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39,41,42,44 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39, 41-42, 44, and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 3, 2009 has been entered.

Claims 39, 41-42, 44, and 46 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39, 41-42, 44, and 46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treating of infection caused by bacteria and malaria, does not reasonably provide enablement for a method of treating infection caused by other infectious agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In the instant case, the specification fails fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In*

re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to provide information allowing the skilled artisan to ascertain these compounds possessing the recited, and claimed, physiological activity without undue experimentation.

1) the quantity of experimentation necessary,

. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all infectious agents including, but not limited to, fungus, virus, and parasites, necessitating an exhaustive search for all embodiments, regardless their chemical formula, or structure, suitable to practice the claimed invention. Examiner notes the claims read on all

infections caused by various infectious agents, disclosed, or undisclosed, regardless the pathophysiology and pathogenesis of these diseases.

2) the amount of direction or guidance provided,

In the instant case, only malaria treatment method is set forth, thereby failing to provide sufficient working examples. The instant specification only discloses one disease, i.e., malaria that can be treated with the herein claimed compounds. Absent that one disease herein disclosed, the instant specification is silent as to using those herein claimed compound genera encompassed by the instant claims.

3) the presence, or absence, of working examples,

Applicant fails to provide information allowing the skilled artisan to ascertain the disease states treatable by the herein claimed compounds without undue experimentation. In the instant case, only one infection example is set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define those disease states treatable by the herein claimed compounds, as required by those guidelines set forth in *In re Wands*, supra. Absent exemplification providing guidance as to these diseases herein envisioned, the instant specification fails to provide a method of treating those disease states possessing various pathophysiology and etiologies in the skilled artisan's possession, absent undue experimentation.

4) the nature of the invention,

The instant invention reading on all possible disease states caused by any infectious agents envisioned, disclosed, or undisclosed, set forth a broad inventive scope.

5) the state of the prior art,

The instant claims read on all disease states caused by any infectious agent, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Although one example is set forth, no information is provided to guide the skilled artisan to treat those diverse disease states. Examiner is unaware of any nexus, stated in the art, or herein disclosed, attributing the herein envisioned physiological activity to the treatment of a vast array of infection diseases. Simply stated the skilled artisan must employ experimentation to discover treatment for these diverse diseases required to practice the claimed invention.

6) the relative skill of those in the art

The relative skill of those in the art is generally considered high.

7) the predictability of the art,

The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. Disease states herein claimed do not flow from a single biochemical lesion, but from a range of different infectious agents. The instant claimed malady has no succinct etiological underpinnings, thus the recited conditions are not ameliorated by effecting a single biochemical lesion. That the instant malady is not attributable to a single etiology or infectious agent, with the basis of the disease stated diffuse and multifaceted, the skilled artisan must teat each compound

against the envisioned biochemical lesion to determine the possible use of such compounds in the instant invention.

8) the breadth of the claims.

. The instant claims read on all infectious diseases caused by any infectious agents, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicant's claims encompass every, and all infections regardless the etiology or causative agents or organisms. Applicants fail to provide information sufficient to identify the infection disease treatable by the herein claimed compounds to practice the claimed invention, absent undue experimentation.

Response to Arguments

Applicant's arguments filed June 3, 2009 averring one of skilled in the art would be able to screen the compounds for the treatment of the herein claimed various infections have been fully considered but they are not persuasive. The examiner notes that the instant specification only disclose one mechanism of action as to how the herein claimed compounds work. The examiner is not aware of any nexus between the various infectious agents and the instant disclosed mechanism of action in the state of the art. There is no working example other than the treatment of malaria. It is not clear what kind of infection would be treatable with compounds having the instant disclosed mechanism of action. Without guidance, working examples, and taking with the state of the art and the breadth of the instant claims, one of skilled in the art would not have

practiced the instant invention in full scope. Therefore, the rejection of 35 USC 112, first paragraph is deemed proper.

The term "subject susceptible to infection" is contrued as any subject since any subject is susceptible to infection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 39, 41-42, 44, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,206,156 ('156).

'156 teaches the herein claimed organophosphorus compounds – the method of preparing such compounds and the administration of such compounds being useful in treating microbial infection (See col. 71, line 65 – col. 72, line 22, also col. 2, lines 25-45).

By administering the compounds in '156 to a subject with microbial infection, the instant recited limitation is met since the subject does not have to be infected by fungi, virus, parasites, or malaria. Examiner will favorably consider amendments to the claims citing "a method of treating virus, fungal, parasitic infection". Such amendment will obviate the rejection under 35 USC 102(b).

Double Patenting

Applicant's remarks with regard to the double patenting rejection are acknowledged. Therefore, the outstanding double patenting rejections are maintained.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 39, 41-42, 44, and 46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,534,489 ('489). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '489 recited the herein claimed compounds and the method of using such compounds in treating infection caused by bacteria, virus, fungi, and parasites.

Response to Arguments

Applicant's remarks filed June 3, 2009 with regard to the double patenting rejection is acknowledged. Accordingly, the rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon - Fri from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

San-ming Hui
Primary Examiner
Art Unit 1617

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